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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,721	02/15/2001	Arne Hengerer	P00,1220	2618
26574	7590	09/10/2007		
SCHIFF HARDIN, LLP PATENT DEPARTMENT 6600 SEARS TOWER CHICAGO, IL 60606-6473			EXAMINER GILLIGAN, CHRISTOPHER L	
			ART UNIT 3626	PAPER NUMBER
			MAIL DATE 09/10/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/784,721	<b>Applicant(s)</b> HENDERER ET AL.	
	<b>Examiner</b> Luke Gilligan	<b>Art Unit</b> 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-20 is/are pending in the application.
- 4a) Of the above claim(s) 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-15 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Response to Amendment***

1. In the amendment filed 9/18/06, the following has occurred: claims 1, 12, 14, and 15 have been amended and claim 20 has been added. Now, claims 1, 2, 4-15 and 20 are presented for examination with claims 16-19 withdrawn from consideration.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 2, 4-15 and 20 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

4. Claim 1 recites "a central laboratory...for automatically reporting back a listing to said treating physician of secondary examinations available for acting on said point of care laboratory measurement data...if an initial evaluation at said expert system of said point of care laboratory measurement data does not produce a definitive diagnosis." Claim 12 recites "a central expert system including access to a data bank for examining the point of care laboratory measurement data and for assessing sufficiency of said patient specimen for preparing a definite diagnosis and at least one secondary examination." The originally filed specification would not have enabled one of ordinary skill in the art to make or use the claimed invention without undue experimentation because it is unclear how the central expert system determines the sufficiency of the point of care laboratory measurement data to produce a definitive

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diagnosis and it is unclear how the central expert system or the central laboratory determines what secondary examinations should be reported back to the physician.

5. Page 5 of the specification indicates that "intelligent algorithms" or interpretation "dependent on data deposited in electronic data files 3" may be used by the central expert system to assess the measuring result. However, there is no indication of what the "intelligent algorithms" are nor how one of ordinary skill in the art would derive the "intelligent algorithms" without under experimentation. Additionally, there is no indication of how the measuring result would be "interpreted dependent on data deposited in electronic data files 3."

6. Page 6 of the specification gives a couple of example reasons why measurement values may not be sufficient for preparing a diagnosis but does not give any disclosure on how the central expert system would reach these conclusions. In other words, there is no disclosure regarding how the central expert system would reach the conclusion that "control reactions for the test (positive or negative controls) or electronic controls of the device are recognized as incorrect or the supposition that a disease is present that cannot be identified in the POC unit 1."

7. Page 6 of the specification further indicates that in the case of insufficient diagnosis, the expert system communicates with central laboratories regarding capacity for secondary examinations. The specification also indicates that the secondary examinations can be of alternative or supplementary nature but there is no disclosure how it is determined what the secondary examinations should be. There is no disclosure regarding whether it is the central expert system or the central laboratories who makes this determination nor regarding how either one would make the determination. Therefore, one of ordinary skill in the art would not have been enabled to make or use the claimed invention at the time of the invention.

8. Claims 2, 4-11, 13-15, and 20 are rejected for the same reasons as claims 1 and 12 through dependency.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 2, 4-7, 12-15, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pestonik et al., U.S. Patent Application Publication No. 2004/0260666 in view of Diamond et al., U.S. Patent No. 5,692,220.

11. As per claim 1, Pestonik teaches a networked expert system for automatic evaluation and quality control of medical point of care laboratory measurement data comprising: a point of care measuring device disposed at a point of care which obtains point of care laboratory measurement data (see paragraph 0028, i.e. gathered patient data); a central expert system, disposed remote from said location of point of care, and a data link, selected from the group consisting of a data line and a data network, connecting said central expert system to said point of care measuring device (see paragraph 0082); said central expert system being accessible by a treating physician via said data link to function as a virtual laboratory data collection and diagnostic system for acting on said point of care laboratory measurement data to make an evaluation available to said treating physician based on said point of care laboratory measurement data (see paragraph 0084); and a central laboratory connected online to said expert system for automatically reporting back a decision-supported patient data including medical care recommendations to said treating physician (see paragraph 0084). Pestonik does not explicitly teach said point of care laboratory measurement data is of a patient specimen. Pestonik also does not explicitly teach the central laboratory reporting back a listing to of

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secondary examinations available for acting on said point of care laboratory measurement data to make evaluation available to said treating physician based on said point of care laboratory measurement data if an initial evaluation at said expert system of said point of care laboratory measurement data does not produce a definitive diagnosis.

12. Diamond teaches a decision support system including a point of care measuring device disposed at a point of care which obtains point of care laboratory measurement data (see column 2, lines 57-59); and a central laboratory automatically reporting back a listing to of secondary examinations available for acting on said point of care laboratory measurement data to make an evaluation available to said treating physician based on said point of care laboratory measurement data if an initial evaluation of said point of care laboratory measurement data does not produce a definitive diagnosis (see column 3, lines 15-30, since the results of the additional suggested tests are compared to any previous results, the Examiner interprets the additional tests to be available for acting on said point of care laboratory measurement data). It would have been obvious to one of ordinary skill in the art at the time of the invention incorporate such a feature into the system of Pestonik. One of ordinary skill in the art would have been motivated to incorporate such a feature for the purpose of aiding in the objective of eliminating the need to re-input patient data each time a clinician examines the same patient (see paragraph 0011 of Pestonik).

13. As per claim 2, Pestonik in view of Diamond teaches the system of claim 1 as described above. Pestonik further teaches said point of care measuring device is disposed at a facility of a physician (see paragraph 0071).

14. As per claim 4, Pestonik in view of Diamond teaches the system of claim 1 as described above. Pestonik does not explicitly teach the central laboratory reports the results of the secondary examinations to the expert system and the expert system re-evaluates the point of

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care laboratory measurement data by using the results of the secondary examinations.

Diamond further teaches the central laboratory reports the results of the secondary examinations to the expert system and the expert system re-evaluates the point of care laboratory measurement data by using the results of the secondary examinations (see column 3, lines 6-14). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Pestonik for the reasons given above with respect to claim 1.

15. As per claim 5, Pestonik in view of Diamond teaches the system of claim 1 as described above. Pestonik does not explicitly teach a request to the point of care is automatically made for providing a sample for the central laboratory. Diamond further teaches a request to the point of care is automatically made for providing a sample for the central laboratory (see column 3, lines 20-30). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Pestonik for the reasons given above with respect to claim 1.

16. As per claim 6, Pestonik in view of Diamond teaches the system of claim 1 as described above. Pestonik further teaches a plurality of sub-systems forming said central expert system connected to each other via a data network using data encoding (see paragraph 0071).

17. As per claim 7, Pestonik in view of Diamond teaches the system of claim 1 as described above. Pestonik further teaches said expert system includes a data bank containing up-to-date medical knowledge and patient data and acts on said point of care laboratory measurement data using said medical knowledge and said patient data (see paragraph 0028).

18. As per claim 12, Pestonik teaches a networked expert system for automatic evaluation and quality control of medical point of care laboratory measurement data, comprising: a communications interface for receiving a message including a point of care laboratory

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measurement data (see paragraph 0028); a central expert system including access to a data bank for examining the point of care laboratory measurement data (see paragraph 0082); a data bank containing up-to-date medical knowledge and patient data (see paragraph 0028); an input processor for receiving data comprising a diagnostic evaluation of the point of care laboratory measurement data and therapy concepts and background knowledge (see paragraph 0084); and a distribution processor for forwarding the received diagnostic evaluation data and therapy concepts and background knowledge to a destination system (paragraph 0084).

19. Pestonik does not explicitly teach assessing sufficiency of said patient specimen for preparing a definite diagnosis and preparing at least one secondary examination. Diamond teaches a decision support system including a point of care measuring device disposed at a point of care which obtains point of care laboratory measurement data (see column 2, lines 57-59); and a central expert system for assessing sufficiency of said patient specimen for preparing a definite diagnosis and at least one secondary examination (see column 3, lines 15-30). It would have been obvious to one of ordinary skill in the art at the time of the invention incorporate such a feature into the system of Pestonik. One of ordinary skill in the art would have been motivated to incorporate such a feature for the purpose of aiding in the objective of eliminating the need to re-input patient data each time a clinician examines the same patient (see paragraph 0011 of Pestonik).

20. Claims 13-15 contain substantially similar additional limitations to those already addressed in claims 1, 2, and 4 and, as such, are rejected for similar reasons as given above.

21. As per claim 20, Pestonik in view of Diamond teaches the system of claim 1 as described above. Pestonik does not explicitly teach the secondary examinations feature as described above. Diamond further teaches said secondary examinations include at least one of: an alternative secondary examination wherein parameters used in secondary evaluation of



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said data are equal to said initial evaluation but are determined by a method different from said initial evaluation; and a supplemental secondary examination wherein parameters used in said secondary examinations are different than parameters used in said initial evaluation and which are not to be determined by said point of care measuring device (see column 3, lines 15-30). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Pestonik for the reasons given above with respect to claim 1.

22. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pestonik et al., U.S. Patent Application Publication No. 2004/0260666 in view of Diamond et al., U.S. Patent No. 5,692,220 and further in view of Stewart et al., U.S. Patent No. 6,383,150.

23. As per claim 8, Pestonik in view of Diamond teaches the system of claim 6 as described above. Pestonik does not explicitly teach said central expert system includes means for limiting access to up-to-date medical knowledge and patient data only to authorized persons. Stewart teaches a central expert system that includes means for limiting access to up-to-date medical knowledge and patient data only to authorized persons see column 7, lines 63-35). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Pestonik. One of ordinary skill in the art would have been motivated to include such a feature for the purpose of protecting patient data.

24. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pestonik et al., U.S. Patent Application Publication No. 2004/0260666 in view of Diamond et al., U.S. Patent No. 5,692,220 and further in view of Jachimowicz et al., U.S. Patent No. 5,763,862.

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25. As per claim 9, Pestonik in view of Diamond teaches the system of claim 7 as described above. Pestonik does not explicitly teach at the location of said treating physician, a chip card reader which requires insertion of a chip card of an authorized user in order to authorize access to said central expert system. Jachimowicz teaches a chip card reader which requires insertion of a chip card of an authorized user in order to authorize access to said central expert system (see column 3, lines 44-48). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this data security means into the system of Pestonik. One of ordinary skill in the art would have been motivated to incorporate this element for the purpose of enhancing security of sensitive data located at various locations (see column 3, lines 52-59 of Jachimowicz).

26. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pestonik et al., U.S. Patent Application Publication No. 2004/0260666 in view of Diamond et al., U.S. Patent No. 5,692,220 and further in view of Stevens et al., U.S. Patent No. 6,599,481.

27. As per claim 10, Pestonik in view of Diamond teaches the system of claim 1 as described above. Pestonik does not explicitly teach a container for obtaining a patient specimen having an electronically readable identifier thereon. Stevens teaches a container for obtaining a patient specimen having an electronically readable identifier thereon (see column 4, lines 1-12). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Pestonik. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of facilitating more efficient processing of handling operations within a laboratory (see column 4, lines 6-7 of Stevens).

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28. As per claim 11, Pestonik in view of Diamond and Stevens teaches the system of claim 10 as described above. Pestonik does not explicitly teach said electronically readable identifier is a bar code. Stevens further teaches said electronically readable identifier is a bar code (see column 4, lines 1-12). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Pestonik for the reasons given above with respect to claim 10.

### ***Response to Arguments***

29. Applicant's arguments with respect to claims 1, 2, 4-15 and 20 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***


30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (571) 272-6770. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

31. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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32. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

8/31/07

  
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